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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,801	07/21/2006	Gordon Dawson	11123.0108USWO	8782

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EXAMINER	
SULLIVAN, DANIELLE D	
ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,801	DAWSON ET AL.	
	Examiner	Art Unit	
	DANIELLE SULLIVAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,13-20 and 23-32* is/are pending in the application.

4a) Of the above claim(s) *23-25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-20 and 26-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/21/06, 11/02/2006, 12/29/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 23-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected process claims, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/17/2009.

Applicant's election without traverse of Group I in the reply filed on 12/17/2009 is acknowledged.

Claims 1-10 and 13-20, 26-32 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites from 60% to about 98% by weight, preferably from about 70% to about 95% by weight, and most preferably from about 74% to about 90% by weight. Claim 10 recites that the particles of fibrate have an average size of less than about 20 um, preferably of less than about 10 um. It is unclear if the terms "preferably" and "most preferably" in claims 5 and 10 add further weight to the smaller ranges. Hence, the metes and bounds of the claims cannot be determined.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7, 14-20, 26 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Junien et al. (EP 1424070).

Applicant's Invention

Applicant claims a composition comprising particles of metformin and fibrate, wherein the composition comprises at 70-95% by weight metformin and fibrate with 5-30% by weight excipients, and the ratio of metformin to fibrate is between 500:90 and 850:35, and wherein the fibrate is selected from fenofibrate or fenofibric acid, and with the proviso that if the ratio is between 500:95 and 500:65, said composition comprises a dispersion aid. Claims 2 and 3 limit the ratio to from 500:54 and 850:65 or 850:54 and 850:35, respectively. Claim 4 and 32 are directed towards the inherent properties of the composition. Claim 5 specifies the composition comprises 74-90% fibrate and metformin combined and from about 10-26% excipients. Claim 7 limits the fibrate to fenofibrate. Claims 15 and 26 specify ratios within the range. Claims 16-18 specify the formulation may be in different forms, including a tablet or capsule. Claim 19 specifies the weight of a tablet is 500-1500 mg. Claim 20 specifies the composition further comprises an active selected from PPAR activators.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

Junien et al. teach a composition comprising metformin and a PPAR agonist, preferably fenofibrate [0013, 0030]. The term PPAR agonist is equivalent to a PPAR activator [0009]. The metformin is in the range of one to twenty times the mass of the PPAR agonist [0038]. The formulation may be formulated as a powder which is an admixture of the active with the solid particles [0046]. Dispersants and other excipients may be added [0049]. The dosage may be formulated as a liquid solution, suspension or emulsion or a capsule, tablet, powder or lozenge [0047-0050].

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Junien et al. do not teach the specific ranges, however in view of In re Aller, Lacey, and Hall, 105 USPQ 233 (C.C.P.A. 1955), "change in concentration is not patentable modification, however, such changes may impart patentability to process if ranges claimed produce new and unexpected results". Since, the present invention is utilized for the same purpose, a pharmaceutical formulation, one of ordinary skill in the art would have been able to adjust the formulation to the specific ratios. Hence, the present claims are prima facie obvious.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Junien et al. adjust the ingredients into compositions comprising particles of metformin and fibrate, wherein the composition comprises at 70-95% by weight metformin and fibrate with 5-30% by weight excipients, and the ratio of metformin to fibrate is between 500:90 and 850:35, and wherein the fibrate is selected from fenofibrate or fenofibric acid, and with the proviso that if the ratio is between 500:95 and 500:65, said composition comprises a dispersion aid. One of ordinary skill would be able to utilize the teachings to formulate different formulations of the metformin and fibrate by adjusting the amounts of the individual components.

Claims 6, 8-10, 13 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Junien et al. (EP 1424070) in view of Stamm et al. (US 6,531,158).

Applicant's Invention

Applicant claims a composition comprising particles of metformin and fibrate, wherein the composition comprises at 70-95% by weight metformin and fibrate with 5-30% by weight excipients, and the ratio of metformin to fibrate is between 500:90 and 850:35, and wherein the fibrate is selected from fenofibrate or fenofibric acid, and with the proviso that if the ratio is between 500:95 and 500:65, said composition comprises a dispersion aid. Claims 6 specifies the fibrate is crystalline or amorphous. Claim 8 specifies the fibrate is micronized or co-micronized. Claim 9 specifies the fibrate is co-micronized with a surfactant. Claim 10 specifies the fibrate has an average particle size of less than 20um. Claims 13 and 28-31 specify the fibrate is in the form of

nanoparticles having an average size of about 2000nm to about 100nm. Claim 27 specifies the fibrate has an average particle size of less than 10um.

Determination of the scope and the content of the prior art

(MPEP 2141.01)

The teachings of Junien et al. above 103 rejection.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Junien et al. do not teach the fibrate is crystalline or amorphous. Neither is the fibrate taught as being co-micronized. The average particle size of less than 20 or 10um is not taught. It is for this reason that Stamm et al. is joined.

Stamm et al. teach a fenofibrate composition which has high bioavailablility and a method of preparing it (abstract). Since fenofibrate is poorly absorbed in the digestive tract there is a need to improve its bioavailability (column 1, lines 26-29). The fenofibrate is micronized to a size of less than 20um or 10 um (column 3, lines 13-20, 46-48). The preferred surfactant, sodium laurylsulfate, is co-micronized with fenofibrate. (column 4, lines 38 and 39). The fenofibrate particles granulated are crystalline (column 5, lines 58-67).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Junien et al. and Stamm et al. to utilize fenofibrate

which is crystalline, has an average particle size of less than 20 or 10um which is co-micronized in a surfactant because Stamm et al. teaches that fenofibrate granulated with these properties has a higher bioavailability. Hence, it would have been obvious to utilize the teachings of Stamm et al. to include fenofibrate with the above properties in order to improve the absorption of the drug in the digestive tract.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bonhomme et al. (US 6,372,790) and Teng et al. (US 6,531,158).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danielle Sullivan whose telephone number is (571) 270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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